[redacted]

Date Mailed: 11/21/2022
MOAHR Docket No.: 22-004405
Agency No.: 89751634
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Aaron McClintic

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.,* and upon Petitioner's request for a hearing.

After due notice, a telephone hearing was held on October 27, 2022. [redacted] appeared and testified on her own behalf. Leigha Burgdorff, Appeals Review Officer, represented the Respondent Department of Health and Human Services (DHHS or Department). Alanna Velandra, Review Analyst, and Dr. David Wartinger testified as witnesses for the Department.

During the hearing, the Department offered one evidence packet/exhibit that was admitted into the record as Exhibit A, pages 1-39.

ISSUE

Did the Department properly deny Petitioner's prior authorization request for intrathecal Spinraza/Nusinersin injections?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material, and substantial evidence on the whole record, finds as material fact:

1. Petitioner is a twenty-seven-year-old Medicaid beneficiary who has been diagnosed with spinal muscular atrophy type II (Exhibit A, page 12).

2. On July 26, 2022, the Department received a prior authorization request for intrathecal Spinraza/Nusinersin injections (Exhibit A, pages 6-7).

3. As part of that request and its supporting documentation, the provider stated in part:

> [redacted] has previously been treated with Spinraza with reported improvement in strength… Without treatment [redacted] genetic disease will continue to cause avoidable loss of function and early death. This is preventable with available FDA approved treatments being denied to her by this policy.

Exhibit A, page 7

4. On July 28, 2022, the Department sent Petitioner written notice that the request had been denied on the basis that "At this time, Spinraza is covered under EPSDT guidelines, which covers Medicaid eligible beneficiaries younger than 21 years of age. Additionally, in order for Medicaid to cover injectable drugs and biologic agents, there must be sufficient clinical evidence demonstrating the effectiveness and safety of the drug or biological product. No objective evidence has been submitted that demonstrates benefits to this particular beneficiary from her prior use of the drug from 2020" (Exhibit A, page 9).

5. On September 28, 2022, the Michigan Office Administrative Hearings and Rules (MOAHR) received the request for hearing filed in this matter regarding the Department's decision. (Exhibit A, pages 4-5).

6. The medical order documentation included in the exhibits states the following: "The present mobility device, features and components continue to meet the beneficiary's current medical conditions and functional needs." (Exhibit A, p.19)

CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statutes, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

Medicaid covered benefits are addressed for the practitioners and beneficiaries in the Medicaid Provider Manual (MPM) and, in part, the applicable version of the MPM states:

> **SECTION 1 – GENERAL INFORMATION** Federal regulations require state Medicaid programs to offer early and periodic screening, diagnosis, and treatment (EPSDT) services to Medicaid eligible beneficiaries younger than 21 years of age; however,

beneficiary participation is voluntary. The intent of EPSDT is to provide necessary health care, diagnostic services, treatment, and other measures according to section 1905(a) and 1905(r) [42 U.S.C. 1396d] of the Social Security Act (1967) to correct or ameliorate defects and physical and mental illnesses and conditions discovered whether or not such services are covered under the state plan. State Medicaid programs are required to provide for any services that are included within the mandatory and optional services that are determined to be medically necessary for children under 21 years of age. MPM Early and Periodic Screening Diagnostic and Treatment, 7/1/22

3.16.A. COVERAGE OF THE INJECTABLE [RE-NUMBERED 7/1/22]

Medicaid covers injectable drugs and biological products administered by a physician in the office, clinic setting, and in the beneficiary's home. The drug or biological product must be Food and Drug Administration (FDA) approved and reasonable and necessary according to accepted standards of medical practice for the diagnosis or treatment of the illness or injury of the beneficiary. There must be sufficient clinical evidence demonstrating the effectiveness and safety of the drug or biological product.
An injectable drug is covered if the drug is:

* Specific and effective treatment for the condition for which it is being given.
* An immunization administered for travel to a foreign country is not a Medicaid-covered benefit.
* Given for the treatment of a particular documented diagnosis, illness, or condition (e.g., vitamin injections which are not specific replacement therapy for a documented deficiency or disease and are given simply for the general good and welfare of the patient).
* Administered by the recommended or accepted administration method for the condition being treated.
* Administered according to the recommended dosing schedule and amount for the condition being treated.

For any injectable drug that a practitioner purchases directly through a pharmacy, distributor or wholesaler which is administered in the office, clinic setting, or the beneficiary's home, the injectable drug is considered a physician service rather than a pharmacy benefit. The physician must not send the beneficiary to a pharmacy to obtain an injectable drug. If a pharmacy sells injectable drug products to a physician, the pharmacy must obtain payment directly from the purchasing physician. MDHHS allows a select list of physician-administered drugs to be covered through the pharmacy benefit as identified in the Special Product Coverage section of the Pharmacy Chapter. If the

practitioner uses a pharmacy to acquire the drug for administration, the pharmacy must submit the claim as a pharmacy claim. (Refer to the Special Product Coverage section of the Pharmacy chapter for additional information.)

If the beneficiary has other insurance that allows the injectable drug product to be obtained at the pharmacy by the beneficiary, then the other insurance rules (e.g., Medicare Part D) must be followed; however, the reimbursement of the beneficiary's liability (i.e., coinsurance/deductible/ copay) may be covered as a physician service. When administering a dose drawn from a multidose vial, only the amount administered to the beneficiary is covered. If a drug is only available in a single use vial and any drug not administered must be discarded, the amount of the drug contained in the vial is covered. MPM Practitioner, pp. 19-20, 7/1/22

Here, as discussed above, Petitioner's request for intrathecal Spinraza/Nusinersin injections was denied pursuant to the above policies and on the basis that she is older than 21 years old and failed to demonstrate through objective medical evidence that the injections were beneficial to her when she previously received the injections.

In appealing the denial, Petitioner bears the burden of proving by a preponderance of the evidence that the Department erred in denying her prior authorization request. Moreover, the undersigned Administrative Law Judge is limited to reviewing Department's decision in light of the information available at the time the decision was made.

Given the record and applicable policy in this case, Petitioner has failed to meet her burden of proof and the Department's decision must be affirmed.

During the hearing, the Department's witness credibly and fully explained why the request was denied. In particular, she noted that Petitioner failed to provide any medical records from when she was previously receiving injections to confirm that the injections had been beneficial to her.

Petitioner testified that she made several attempts to obtain the medical records from her physician in Wisconsin, during the time period when she was previously receiving injections, but she was unable to obtain the medical records. Petitioner testified at hearing that she had improvement in her physical functioning when she previously received the injections and in some of the diagnostic testing. Dr. Wartinger testified at hearing that without the previous medical records there was no objective medical evidence that the injections stabilized or improved Petitioner's condition. Petitioner was advised that if she was able to locate her previous medical records, she could submit them with a new prior authorization request.

With respect to the decision at issue in this case, the Department's decision must be affirmed given the available information and applicable policies.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that the Department properly denied Petitioner's prior authorization request.

IT IS, THEREFORE, ORDERED that:

The Department's decision is **AFFIRMED.**

AM/sj

Aaron McClintic
Administrative Law Judge

NOTICE OF APPEAL: A party may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Office of Administrative Hearings and Rules (MOAHR).

A party may request a rehearing or reconsideration of this Order if the request is received by MOAHR within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MOAHR will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MOAHR. If submitted by fax, the written request must be faxed to (517) 763-0155; Attention: MOAHR Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Office of Administrative Hearings and Rules
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

Via Electronic Mail:

DHHS Department Contact
Gretchen Backer
400 S. Pine, 6th Floor
Lansing, MI 48909
MDHHS-PRD-Hearings@michigan.gov

DHHS Department Representative
M. Carrier
Department Community Health
MDHHS
Lansing, MI 48909
MDHHS-Appeals@michigan.gov

Agency Representative
Leigha Burghdoff
MDHHS Appeals
P.O. Box 30807
Lansing, MI 48909
MDHHS-Appeals@michigan.gov

Via First Class Mail:

Petitioner
[redacted]